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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534
7590	06/18/2009		EXAMINER	
Edward G Greive Renner Kenner Greive Bobak Taylor & Weber Fourth Floor First National Tower Akron, OH 44308-1456			WOODALL, NICHOLAS W	
		ART UNIT	PAPER NUMBER	
		3775		
			MAIL DATE	DELIVERY MODE
			06/18/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/534,567	BIEGUN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nicholas Woodall	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) \_\_\_\_ is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date ____ .	6) <input type="checkbox"/> Other: ____ .

## DETAILED ACTION

1. This action is in response to applicant's amendment received on 03/16/2009.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 15, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisser (U.S. Patent 5,454,815).

Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone. The plastic material is hard enough to rasp the bone and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. The examiner would like to note that Geisser discloses the device can be made from polyamides, which is a specific material listed by the applicant in the specification (page 3 lines 7-9). Therefore, the device inherently has the capability of deteriorating at 137 degrees Celsius, since they are made from the same materials. Also, the examiner would like to note that Geisser discloses that all rasps dull during use and that any dullness is a considerable disadvantage suggesting that all rasps wear out after a single use causing significant problems such as longer operation time and overheating (see

column 1 lines 29-35). Geisser than discloses his invention directed to a single use plastic rasp that will be discarded after use to alleviate the need for sterilization and cleaning (see column 1 lines 61-64). Therefore, the examiner believes Geisser clearly discloses a device that wears out after a single use and is then discarded.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Judd (U.S. Patent 1,396,934).

Geisser discloses the invention as claimed except for the insert being made from a metal. Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Judd teaches a device made from a plastic material including a metallic reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Because both Geisser and Judd teach devices comprising reinforcing inserts for plastic materials, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one reinforcing insert with the other in order to achieve the predictable result of reinforcing the plastic material.

The device of Geisser and modified by Judd disclose the invention as claimed except for the insert being made from a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser as modified by Judd wherein the insert is made from a shape memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

6. Claims 12, 13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses a method comprising the steps of providing a body made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone, wherein the plastic is hard enough to rasp the bone and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. Geisser fails to disclose the method further comprising the step of exposing the device to gamma or beta radiation. Morgan teaches a method comprising the step of exposing a device to gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Geisser further comprising the

step of exposing the device to gamma radiation in view of Morgan in order to sterilize the device.

***Response to Amendment***

7. The declaration under 37 CFR 1.132 filed 03/16/2009 is insufficient to overcome the rejection of claim 21 based upon 35 U.S.C. 102(b) as set forth in the last Office action because: the applicant's statement that the prior art reference does not have a hardness capable of removing bone is not persuasive. First, the applicant states that the prior art rasp prior to being treated with the radiation is not hard enough to remove bone and therefore does not meet the limitations of claim 21 is not persuasive. As the examiner pointed out in the previous office action and above, the prior art teaches that the rasp is made from the same material as the current application and the prior art further comprises that the prior art is used to remove bone material. Therefore, the prior art clearly discloses the raps being made from the same material and is used to remove bone, which clearly reads upon the limitations of claim 21. Second, the applicant is comparing the prior art device to the current invention after the current invention has been treated with radiation, which makes the current invention harder than the prior art as discussed in the specification of the current application. The examiner would like to note that claim 21 does not require the device to be treated with radiation, and therefore the comparison is not proper. Claim 21 only requires a device made from a similar material used to remove bone and wear out after a single use as discussed in the previous office action and above. The prior art discloses all the limitations of claim 21 as presented and the affidavit is not sufficient to overcome the prior art reference.

***Response to Arguments***

8. Applicant's arguments filed 03/16/2009 have been fully considered but they are not persuasive. The applicant's argument directed to claim 21 are discussed above in relation to the affidavit filed on 03/16/2009. These arguments are not persuasive. The applicant's arguments that the Geisser reference and the Judd reference are not analogous prior art is not persuasive. MPEP 2141 states, "Furthermore, prior art that is in a field of endeavor other than that of the applicant (as noted by the Court in KSR, "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one", 550 U.S. at \_\_\_, 82 USPQ2d at 1396 (emphasis added)), or solves a problem which is different from that which the applicant was trying to solve, may also be considered for the purposes of 35 U.S.C. 103. (The Court in KSR stated that "[t]he first error...in this case was...holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter...The second error [was]...that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." 550 U.S. at \_\_\_, 82 USPQ2d at 1397. Federal Circuit case law prior to the Supreme Court's decision in KSR is generally in accord with these statements by the KSR Court. See e.g., In re Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (en banc) ("[ I ]t is not necessary in order to establish a *prima facie* case of obviousness that both a structural similarity between a claimed and prior art compound

(or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant"); *In re Lintner*, 458 F.2d 1013, 1018, 173 USPQ 560, 562 (CCPA 1972) ("The fact that [applicant] uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be *prima facie* obvious from the purpose disclosed in the references.").).

Therefore, just because the two references are not in the same field of prior art does mean that one having ordinary skill in the art would not combine the teachings of the references, i.e. using carbon fibers to reinforce a plastic element. The applicant's argument that one having ordinary skill in the art would not use the teachings of Morgan to sterilize the Geisser reference because Geisser discloses a one use rasp that is not cleaned or sterilized after use is not persuasive. The applicant is correct that Geisser discloses a one time rasp that is not sterilized or cleaned after use, but Geisser clearly discloses the rasp is sterilized after manufacturing and prior to packaging (column 1 lines 64-66). Therefore, the examiner believes that one having ordinary skill in the art would use the teachings of Morgan to sterilize the Geisser device with radiation prior to packaging the device. The examiner has not provided any new grounds of rejection making this office action **FINAL**.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
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